REMARKS

In the Office Action dated April 23, 2002, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct inventions:

I. Claims 4-8 and 10-13, drawn to Mts Protein multimers and pharmaceutical compositions thereof, classified in class 530, subclass 350 and class 514, subclass 2.

II. Claims 14, 15, and 19-25, drawn to methods of treatment using Mts protein multimers, classified in class 514, subclass 2.

III. Claims 16-23, drawn to methods of gene therapy, classified in class 435, subclass 455.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 4-8 and 10-13, drawn to Mts protein multimers and pharmaceutical compositions thereof. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent <u>and</u> distinct, 37 C.F.R. §§1.141-142. Without a showing

of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

The Examiner alleges that the proteins of Group I can be used in a materially different process than the method of Group II, such as the generation of antibodies. The Examiner also alleges that the protein multimers of Group I cannot be used in the gene therapy methods of Group III. The Examiner further alleges that the nucleic acids of Group II "have other uses [than the claims of Group III], such as hybridization studies". The Examiner concedes that Groups I and II and Groups II and III are related as a product and process of use.

Applicants respectfully submit that Group II, Claims 14, 15 and 19-25 is drawn to a method of treatment using the Mts protein multimers of Group I. Moreover, the methods of Group III, Claims 16-23 employ a nucleic acid sequence encoding an Mts protein in a method of treating a neurological condition of Group II. Furthermore, the method of Group III, employs the Mts protein of Group I to treat neurological conditions which are the subject of Groups II and III. Therefore, Applicants respectfully submit that the subject matter Groups I-III are linked by a single inventive concept – they are merely different aspects of a single invention. Groups I-III are not "independent and distinct".

Applicants respectfully submit that the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting

grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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